DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 23, 2014

Arthrosurface, Incorporated
Ms. Dawn J. Wilson
Vice President, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K141920
Trade/Device Name: Wrist Hemiarthroplasty System
Regulation Number: 21 CFR 888.3750
Regulation Name: Wrist joint carpal lunate polymer prosthesis
Regulatory Class: Class II
Product Code: KWN, KWO
Dated: November 21, 2014
Received: November 24, 2014

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): **K141920**

Device Name: Wrist Hemiarthroplasty System

Indications for Use:

Indicated for use as a partial replacement of wrist joint(s) disabled by pain, deformity and/or limited motion caused by:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
- Scapholunate Advanced Collapse (SLAC) and other functional deformities
- Trauma, including fractures of the carpal bones

The device is a single use implant intended to be used with bone cement.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	November 21st, 2014
Trade Name:	Wrist Hemiarthroplasty System
Common Name:	Partial Wrist Joint
Device:	Prosthesis, Wrist
Classification Regulation:	Prosthesis, Wrist Carpal Lunate (21 CFR 888.3750) and/or Prosthesis, Wrist Carpal Scaphoid (21 CFR 888.3760) The Arthrosurface Wrist Hemiarthroplasty System requires removal of both the lunate and the scaphoid bones therefore it does not clearly fit one classification.
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	KWN, KWO

Device Intended Use

The Arthrosurface Wrist Hemiarthroplasty System is indicated for use as a partial replacement of wrist joint(s) disabled by pain, deformity and/or limited motion caused by:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis.
- Rheumatoid arthritis.
- Revision where other devices or treatments have failed.
- Scapholunate Advanced Collapse (SLAC) and other functional deformities.

- Trauma, including fractures of the carpal bones.

The device is a single use implant intended to be used with bone cement.

Device Description

The Arthrosurface HemiCAP® Wrist Hemiarthroplasty System consists of a contoured articular implant designed to articulate with the natural radius bone, a taper post and set of instruments used for implant site preparation and delivery. The resurfacing components are manufactured using implant grade cobalt-chrome alloy and will be offered in two diameters, and four articular radii. The taper post is manufactured using implant grade titanium alloy and is offered in one fixed size designed to work with all resurfacing implants.

Substantial Equivalency:

Arthrosurface demonstrated that for the purposes of FDA's regulation of medical devices, the Wrist Hemiarthroplasty System is substantially equivalent in indications and design principles to the following predicate device, which has been previously cleared by the FDA:

Biomet Maestro Carpal Hemi-Arthroplasty (K050028, Cleared on 07/07/08)

The fundamental scientific technology of the proposed device has not changed relative to the predicate device.

- Hemiarthroplasty of the wrist joint
- Same indications for use
- Similar device designs
- Same implant materials

In support of this submission, the following non-clinical tests have been performed on the Subject Device:

- Axial Assembly / Disassembly of Articular and Fixation components
- Resistance to Torque
- Static Compression
- Dynamic Fatigue
- Fretting & Corrosion

The results have demonstrated the safety and effectiveness of the Arthrosurface Wrist Hemiarthroplasty Implants along with substantial equivalence to the predicate device.